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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/566,982

03/22/2006

Marco Tessitore

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EXAMINER

SZMAL, BRIAN SCOTT

ART UNIT

PAPER NUMBER

3736

MAIL DATE

DELIVERY MODE

05/08/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/566,982	TESSITORE ET AL.	
	Examiner	Art Unit	
	Brian Szmal	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-18 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 10-18 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 February 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/2/06</u> . | 6) <input type="checkbox"/> Other: ____. |

Specification

1. The abstract of the disclosure is objected to because the abstract contains claim language, such as the word "said". Correction is required. See MPEP § 608.01(b).

Claim Objections

2. Claim 11 is objected to because of the following informalities: "furthermore" should read as "further" in order to be grammatically correct. Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 10, 12, 15 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Rubinstein et al (5,462,062).

Rubinstein et al disclose a bone marrow biopsy device and further disclose needle arrangement comprising a tubular body, having a proximal end associable with a grip and being provided with an edge free at the opposite end, lamina elements protruding towards said proximal end and movable between a neutral position in which said lamina elements lies near said tubular body and an operating position in which said lamina elements is distanced from said tubular body, wherein said lamina elements is

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formed from a portion of said tubular body; the needle arrangement comprises an outer tubular body extending externally of said tubular body; the lamina elements are triangle-shaped; and the lamina elements are angularly spaced between one another by about 120° (the right edge of 44a is approximately 120° from the right edge of 44d). See Figures 3A-3D.

5. Claims 10, 12, 13 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Stewart (3,175,554).

Stewart discloses a biopsy needle and further discloses needle arrangement comprising a tubular body, having a proximal end associable with a grip and being provided with an edge free at the opposite end, lamina elements protruding towards said proximal end and movable between a neutral position in which said lamina elements lies near said tubular body and an operating position in which said lamina elements is distanced from said tubular body, wherein said lamina elements is formed from a portion of said tubular body; the needle arrangement comprises an outer tubular body extending externally of said tubular body; the outer tubular body comprises protuberances so shaped as to move said lamina elements from said neutral position to said operating position; and the lamina elements are defined by notches that are obtained in said tubular body. See Figures 7, 8 and 10-12.

6. Claims 10, 11 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Kovac et al (DE 3430910 A1).

Kovac discloses a biopsy needle and further discloses needle arrangement comprising a tubular body, having a proximal end associable with a grip and being

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provided with an edge free at the opposite end, lamina elements protruding towards said proximal end and movable between a neutral position in which said lamina elements lies near said tubular body and an operating position in which said lamina elements is distanced from said tubular body, wherein said lamina elements is formed from a portion of said tubular body; the needle arrangement furthermore comprises a window member shaped to enable said sample to be extracted by said device; and the window member has a perimeter defined by a pair of straight margins that are connected at a pair of ends by an arched proximal border and at a pair of opposite ends by an arched distal border. See Figure 1.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 11 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rubinstein et al (5,462,062) as applied to claim 10 above, and further in view of Harris (3,683,892).

Rubinstein et al, as discussed above, disclose a bone marrow biopsy device, but fails to disclose a window member shaped to enable said sample to be extracted by said device; and the window member has a perimeter defined by a pair of straight

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margins that are connected at a pair of ends by an arched proximal border and at a pair of opposite ends by an arched distal border.

Harris discloses a biopsy device and further discloses a window member shaped to enable said sample to be extracted by said device; and the window member has a perimeter defined by a pair of straight margins that are connected at a pair of ends by an arched proximal border and at a pair of opposite ends by an arched distal border. See Figure 1.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the means of Rubinstein et al to include the use of a window, as per the teachings of Harris, since it would provide a means of allowing the user to determine the size of the acquired sample, while allowing access to the sample after the procedure.

9. Claims 11 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stewart (3,175,554) as applied to claim 10 above, and further in view of Harris (3,683,892).

Stewart, as discussed above, disclose a biopsy needle, but fail to disclose a window member shaped to enable said sample to be extracted by said device; and the window member has a perimeter defined by a pair of straight margins that are connected at a pair of ends by an arched proximal border and at a pair of opposite ends by an arched distal border.

Harris discloses a biopsy device and further discloses a window member shaped to enable said sample to be extracted by said device; and the window member has a

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perimeter defined by a pair of straight margins that are connected at a pair of ends by an arched proximal border and at a pair of opposite ends by an arched distal border.

See Figure 1.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the means of Rubinstein et al to include the use of a window, as per the teachings of Harris, since it would provide a means of allowing the user to determine the size of the acquired sample, while allowing access to the sample after the procedure.

10. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stewart (3,175,554) as applied to claim 10 above, and further in view of Wood (2003/0093007 A1).

Stewart, as discussed above, disclose a biopsy needle with an inner stylet slidable within the lumen, but fail to disclose an inner tubular body slidably insertable inside said tubular body.

Wood discloses a biopsy means and further discloses a hollow stylet (28D).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the stylet of Stewart with a hollow stylet, as per the teachings of Wood, since one of ordinary skill in the art would be able to substitute a solid stylet with a hollow stylet without modifying the function of Stewart.

11. Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stewart (3,175,554) as applied to claim 10 above, and further in view of Rubinstein et al (5,462,062).

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Stewart, as discussed above, disclose a biopsy needle, but fail to disclose the lamina elements are triangle-shaped; and the lamina elements are angularly spaced between one another by about 120° .

Rubinstein et al, as discussed above, disclose a bone marrow biopsy device and further disclose the lamina elements are triangle-shaped; and the lamina elements are angularly spaced between one another by about 120° (the right edge of 44a is approximately 120° from the right edge of 44d). See Figure 3D.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the means of Stewart to include triangular shaped elements and spacing the elements apart by about 120° , as per the teachings of Rubinstein et al, since it would provide an alternate shape of the lamina elements, while still providing a means of severing the sampled tissue from the surrounding tissue.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmalec whose telephone number is (571)272-4733. The examiner can normally be reached on Monday-Friday, with second Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian Szmal/
Examiner, Art Unit 3736